

# In the United States Court of Federal Claims

No. 17-850V

(Filed: February 1, 2021)

(Reissued: March 2, 2021)<sup>1</sup>

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A.Y., by his parents and natural guardians,	)
J.Y. and S.Y.	)
 Petitioners,	)
 v.	)
SECRETARY OF HEALTH & HUMAN SERVICES,	)
 Respondent.	)

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*Jeremy Fugate*, United States Department of Justice, Civil Division, Washington, D.C., for Respondent. On the brief were *Ethan P. Davis*, Acting Assistant Attorney General, Civil Division, *C. Salvatore D'Alessio*, Acting Director, *Catherine E. Reeves*, Deputy Director, and *Jennifer L. Reynaud*, Torts Branch, Civil Division, United States Department of Justice, Washington, D.C.

## OPINION AND ORDER

**SOLOMON, Judge.**

On June 22, 2017, Petitioners, [\* \* \*], filed a petition for compensation on behalf of their minor son, A.Y., pursuant to the National Childhood Vaccine Injury Act of 1986

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<sup>1</sup> On February 1, 2021, the Court issued under seal an unredacted version of this opinion and order in accordance with Rule 18(b) of the Vaccine Rules (Appendix B) of the Court of Federal Claims. The Court provided the parties with 14 days to propose redactions. On February 16, 2021, Petitioners filed proposed redactions, ECF No. 60-1, to which the government did not file an objection. The Courts adopts Petitioners' proposed redactions and accordingly reissues this public version of this opinion and order.

(the “Vaccine Act”), 42 U.S.C. §§ 300aa-1 *et seq.* Petitioners alleged that A.Y. experienced a skin rash in 2014 or 2015 because of a varicella vaccine that he received, seven-years earlier, on November 15, 2007. Chief Special Master Corcoran denied the petition, concluding that Petitioners failed to prove by a preponderance of the evidence that: (1) A.Y. actually experienced a reactivation of varicella; (2) varicella could reactivate seven years after vaccination; and (3) given A.Y.’s complicated medical history, that the varicella vaccine caused the alleged post-reactivation symptoms. *A.Y. v. Sec’y of Health & Human Servs.*, 2020 WL 5351342, \*1 (Fed. Cl. Spec. Mstr. June 26, 2020) (ECF No. 45). Petitioners seek review of Chief Special Master Corcoran’s decision, arguing that he abused his discretion in reaching these factual conclusions, that he utilized medical research from outside the pleadings, and improperly declined to credit the opinion of Petitioners’ expert witness. Respondent, the United States, counters that Chief Special Master Corcoran provided a reasonable explanation for his decision and that, in accordance with the highly deferential standard of review applicable to this case, this Court should not second-guess that reasoned decision.

For the reasons explained below, the Court denies Petitioners’ motion for review and sustains the Chief Special Master’s denial of Petitioners’ claim for compensation.

## I. Factual And Procedural Background<sup>2</sup>

### A. A.Y.’s Medical History

On November 14, 2006, A.Y., the eldest of triplets, was born prematurely. *A.Y.*, 2020 WL 5351342 at \*2. He spent the subsequent month in the hospital’s neonatal intensive care unit. *Id.* During that time, he was treated for reflux. *Id.* In November 2007, when A.Y. was one-year old, he received the varicella vaccine. *Id.* He did not experience any immediate symptoms as a result of vaccination. *Id.*

Shortly thereafter, [\* \* \*] became concerned that A.Y. was experiencing developmental delays. *Id.* Beginning in December 2007, A.Y. started receiving speech and occupational therapy through early childhood intervention services; on June 25, 2008, A.Y. was further evaluated for developmental delays at the Helping Hands Clinic in San Antonio, Texas. *Id.* During this time, the [\* \* \*] also became concerned with A.Y.’s gastrointestinal health. *Id.* A.Y.’s pediatrician noted that A.Y. was eating certain solids, but had difficulty with yogurt, cheese, or meat. *Id.* In 2009, A.Y. was evaluated

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<sup>2</sup> For the purpose of resolving the pending motion for review, the Court summarizes the facts as presented in the Chief Special Master’s decision and does not make independent findings of fact. *See, infra*, Section II; *see also Pafford v. Sec’y of Health & Human Servs.*, 64 Fed. Cl. 19, 22 n.4 (2005), *aff’d*, 451 F.3d 1352 (Fed. Cir. 2006).

by Dr. Ricki G. Robinson, a clinical pediatric professor, at Descanso Medical Center for Development and Learning in LeCanada, California, who documented A.Y.'s eating difficulties. *Id.* A.Y. tested negative for celiac disease and his antibody levels were found to be within the normal range. *Id.*

In November 2009, after A.Y. turned three-years old, he was formally diagnosed with autism. A.Y., 2020 WL 5351342 at \*2. In light of this diagnosis and his persistent gastrointestinal issues, the [\* \* \*] took A.Y. to Dr. Jerrold Kartzinel at the Kartzinel Wellness Center in Orlando, Florida for further observations. *Id.* In a July 2010 "to whom it may concern" letter, Dr. Kartzinel asserted that "A.Y. had been diagnosed with epilepsy, gastroesophageal reflux, encephalopathy, metabolism disorder, sleep disorder, immune mechanism disorder, and abnormal feces." *Id.* at \*3. Dr. Kartzinel also recommended a specific diet for A.Y. *Id.*

Over the ensuing four years (from 2010 until 2014), "A.Y. received a dizzying number of treatments and medications." *Id.* A.Y. was administered a "mito cocktail" of supplements to treat a purported mitochondrial/energy processing disorder" and was prescribed numerous medications, including:

- (a) three 90-day courses of Acyclovir/Valtrex (an antiviral drug used primarily for treatment of herpes and chickenpox);
- (b) antibiotics and antifungal medication for "mouthing";
- (c) leucovorin/folinic acid, most commonly used to treat chemotherapy side effects or folate deficiencies;
- (d) Gabapentin/Neurontin (nerve pain medication and anticonversant);
- (e) an attention-deficit/hyperactivity disorder medication; and
- (f) a medication used to treat dementia and Alzheimer's disease.

*Id.* (internal citations omitted). Additionally, "A.Y. received hyperbaric oxygen therapy, a questionably-effective therapy often employed in the treatment of autism[, a]nd in the late fall of 2013, A.Y. received stem cell therapy as well." *Id.* (internal citations omitted). In September 2013, A.Y. was diagnosed with a "cycle of abdominal pain" that "continued off and on, varying in [its] severity." *Id.* To treat his abdominal issues, in late 2014, A.Y. received immunoglobulin and steroid treatments, in addition to stem cell treatments. *Id.*

In January 2015, A.Y., now eight-years old, “developed a rash, starting on his neck and spreading throughout his body.” A.Y., 2020 WL 5351342 at \*4. A.Y.’s pediatrician diagnosed the rash as “*possible* atypical varicella” and prescribed Acyclovir (the same anti-viral medication that A.Y. had received years earlier). *Id.* (emphasis added). The rash “almost cleared up” within a few days; A.Y.’s pediatrician did not conduct testing to confirm the varicella diagnosis. *Id.* On January 8, 2015, in an on-line discussion with Dr. Kartzinel, the [\* \* \*] reported that the rash “[n]ever caused itching or discomfort.” *Id.*

In November 2015, the [\* \* \*] consulted with Dr. Kartzinel again, at which time they discussed A.Y.’s stomach pains and “the beginnings of a chick[en] pox type rash.” *Id.* That same month, Dr. Arthur Krigsman, a gastroenterologist, examined A.Y. as part of a pre-endoscopy and colonoscopy physical. *Id.* at \*5. At this time, the [\* \* \*] claimed that A.Y. had experienced five episodes of “chickenpox lesions” over the past eleventh months but had been successfully treated with Acyclovir. *Id.* Following A.Y.’s endoscopy and colonoscopy, Dr. Krigsman diagnosed him with autism spectrum disorder-associated enteritis. *Id.* Subsequently, Dr. Anne Gershon, a researcher and professor at Columbia University College of Physicians and Surgeons, reviewed the biopsy results from the endoscopy and colonoscopy. *Id.* Dr. Gershon informed Dr. Krigsman that she “found RNA transcripts of 3 [varicella] genes . . . in the intestinal specimens.” *Id.* (bracketed alteration in original). Dr. Gershon advised the [\* \* \*] that A.Y. should take Valacyclovir for his stomach pains and that he should see Dr. Raffi Tachdjian, an allergist and immunologist. *Id.*

In December 2015, Dr. Tachdjian evaluated A.Y. *Id.* Dr. Tachdjian found that A.Y.’s medical history was not entirely consistent with a reactivation of a varicella infection. *Id.* Specifically, he noted that photos of A.Y.’s rash was “not that of classic varicella” and that A.Y. previously had tested negative for antibodies. *Id.* To help with A.Y.’s “poor antibody function,” Dr. Tachdjian prescribed IVIG therapy. *Id.* On February 3, 2016, A.Y. was seen by Dr. Paul Krogstad, a pediatric disease specialist, who opined that while the rashes were “compatible with varicella,” because they quickly cleared up after being treated with Acyclovir, other possible causes, such as viral exanthemas or enterovirus infections, should be considered. *Id.* at \*6. In an August 2016 letter, Dr. Tachdjian reiterated his belief that the cause of A.Y.’s rash was still undetermined but noted that a saliva test performed on A.Y. in February 2016 that tested positive for varicella appeared to corroborate Dr. Gershon’s findings that A.Y. suffered from a “recurrent Varicella infection.” *Id.* at \*5.

## B. Procedural History

### 1. The [\* \* \*] File A Petition For Compensation

On June 22, 2017, the [\* \* \*] filed a petition for compensation pursuant to the Vaccine Act. ECF No. 1. On November 7, 2017, Petitioners filed portions of A.Y.'s relevant medical records but did not complete these records until August 2018.<sup>3</sup> ECF Nos. 7, 8, 26. The [\* \* \*] alleged that A.Y. developed a varicella skin rash in 2014 or 2015 as a result of a varicella vaccine that he received on November 15, 2007. A.Y., 2020 WL 5351342 at \*9. They also alleged that, because of the reactivation of varicella, A.Y. suffered a significant aggravation of his preexisting abdominal and behavioral issues. *Id.* On November 15, 2018, the government filed its report, recommending denying the petition. ECF No. 29. Given the novelty of the [\* \* \*]' claim that varicella vaccine could reactivate seven-years later, Chief Special Master Corcoran ordered additional briefing on that issue and the parties filed timely responses. ECF Nos. 38, 41, 44.

### 2. Expert Testimony

On March 28, 2019, the [\* \* \*], in support of their contentions, presented expert opinion testimony from three doctors: Dr. Robinson, Dr. Richard A. Honaker, and Dr. Gershon. ECF No. 34; *see A.Y., 2020 WL 5351342 at \*6*. Dr. Robinson submitted a three-page report that largely summarized A.Y.'s medical history based on her personal knowledge of his autism-related developmental challenges. *Id.* While Dr. Robinson assumed that A.Y.'s worsening behavioral changes were caused by the varicella reactivation, she did not purport to have "direct knowledge pertaining to *how* a vaccine might result in viral reactivation." *Id.* (emphasis in original). Instead, Dr. Robinson's opinion relied entirely upon Dr. Gershon's opinion that the November 2015 biopsy revealed the same varicella strain as contained in the vaccine that A.Y. received seven-years earlier. *Id.*

Dr. Honaker, who had never treated A.Y. and only reviewed his medical records, likewise was only able offer a medical chronology but could not directly testify as to the likelihood of A.Y. having experienced a varicella reactivation from the vaccine. *Id.* at \*7. He admitted that "he lacks specialization in the medical or scientific areas put into dispute in this case" and recommended "contacting other professionals to conduct a multidisciplinary interaction amongst them to ascertain the issues in this case." *Id.* (internal citations omitted). As part of his report, Dr. Honaker attached an article co-

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<sup>3</sup> Because of deficiencies with these filings, A.Y.'s medical records were refiled on February 20, 2019. ECF Nos 32, 33. Chief Special Master Corcoran noted that even after refiling, it was "impossible to conclude that the records are now complete." *A.Y., 2020 WL 5351342 at \*1 n.4.*

authored by Dr. Gershon, *Varicella-Zoster Virus and the Enteric Nervous System*, 218 J. Infect. Diseases, Supp. 2, S113-19 (Nov. 2018) (the “Gershon Article”), relevant to her opinion of varicella reactivation. A.Y., 2020 WL 5351342 at \*7-\*8. The Gershon Article primarily focused on the latency of the varicella virus but also mentioned “that vaccination has been found to be capable of latency and reactivation.” *Id.* at \*8. Chief Special Master Corcoran noted that the medical articles cited in the Gershon Article for the proposition that varicella vaccine is capable of latency and reactivation were not filed as part of the record. *Id.*

Dr. Gershon offered her expert opinion based on having “researched [Varicella Zoster Virus], Zoster, and latency and reactivation throughout her career.” *Id.* at \*7. In her opinion, “it is medically understood that the wild varicella virus can stay latent for long periods of time . . . but can then be reactivated to cause infection.” *Id.* at \*8. Dr. Gershon presumed that, by extension, the live viral components of the varicella vaccine could act in the same manner. *Id.* Dr. Gershon further reported that after reviewing A.Y.’s 2015 biopsy, she found that he “was experiencing an ‘active’ varicella infection” and that this conclusion was further bolstered by a 2016 saliva test, at which time A.Y. tested positive for varicella. *Id.* Chief Special Master Corcoran noted that that record did not contain a contemporaneous report from Dr. Gershon regarding her analysis of the 2015 biopsy; rather, Dr. Gershon had submitted a one-page report dated November 9, 2017, in which she documented her findings from two years earlier. *Id.* Chief Special Master Corcoran further noted that “[n]o backup materials relating to this [2015] testing” or any evidence of the 2016 saliva tests was submitted for the record. *Id.*

### 3. The Chief Special Master’s Decision

On June 26, 2020, Chief Special Master Corcoran rendered his decision, denying entitlement for compensation. A.Y., 2020 WL 5351342 at \*1. Chief Special Master Corcoran found that, as an initial matter, the [\* \* \*] failed to establish by a preponderance of evidence that A.Y. suffered a varicella-type rash in 2015. A.Y., 2020 WL 5351342 at \*20. Moreover, Chief Special Master Corcoran determined that the [\* \* \*]’ timeframe argument – that there could exist a seven-year gap between the alleged onset of varicella and A.Y. receiving the vaccine – was not medically accepted. *Id.* at \*21. Chief Special Master Corcoran noted that the expert opinions of Drs. Robinson and Honaker did not go to the issue of causation. *Id.* at \*24. While he acknowledged Dr. Gershon’s expert opinion in this matter, Chief Special Master Corcoran ultimately determined that her report based on the 2015 biopsy findings “suffer[s] from reliability concerns” and that her theory of varicella vaccine reactivation was unproven, at least as applied to the facts of this case involving a seven-year gap between vaccination and reactivation. *Id.* at \*20-\*21, \*24. He also found that the “dizzying plethora of treatments” that A.Y. received for his “autism-related developmental problems and

gastrointestinal symptoms" during that seven-year span reasonably could have served as intervening causes for the varicella-like rash. *A.Y.*, 2020 WL 5351342 at \*22.

Finally, Chief Special Master Corcoran concluded that the [\* \* \*] failed to establish, by preponderant evidence, their significant aggravation claim that the varicella vaccine reactivation impacted A.Y.'s preexisting gastrointestinal and behavioral issues. *Id.* at \*22. Chief Special Master Corcoran reasoned that the record evidence supported that A.Y. experienced serious behavioral and gastrointestinal issues *before* the purported 2015 reactivation and that the [\* \* \*] thus had failed to demonstrate that A.Y.'s alleged worsening symptoms were attributable to a reactivation of varicella. Chief Special Master Corcoran also opined that the alleged aggravation of A.Y.'s symptoms could just as likely be attributable to the treatments for "A.Y.'s autism and other conditions that certain of their treaters, like Dr. Krigsman have associated with [autism]." *Id.* at \*22-\*23.

#### **4. Petitioners File A Motion For Review**

On July 27, 2020, Petitioners filed a motion for review of the Chief Special Master's decision pursuant to Rule 23 of the Court of Federal Claims, Appendix B ("Vaccine Rules"). ECF No. 48 ("Pet. Mot.") at 1. In seeking such review, Petitioners argue that the Chief Special Master: (1) abused his discretion by misconstruing A.Y.'s claim as arising from autism instead of a "varicella reactivation causing a varicella-like rash"; (2) abused his discretion by relying on scientific and medical literature that Petitioners did not introduce into the record; and (3) incorrectly required A.Y. to prove his injury by "direct evidence" rather than a "preponderance of the evidence" standard as required by *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). Pet. Mot. at 3. Accordingly, Petitioners ask this Court to reverse the Chief Special Master's decision regarding their varicella reactivation claim, or, in the alternative, remand the case for further consideration. *Id.* at 2. Petitioners did not seek review of the denial of their significant aggravation claim.

On August 26, 2020, the government filed its response to Petitioners' motion for review. ECF No. 51 ("Resp. Br.") at 1. On November 12, 2020, the Court held oral argument. ECF No. 54.

#### **II. Jurisdiction And Standard Of Review**

This Court possesses jurisdiction, pursuant to the Vaccine Act, to review a special master's decision upon the filing of a petition from the unsuccessful party within thirty days of that decision. 42 U.S.C. § 300aa-12(e)(1). The Court may: "(A) uphold the finds of fact and conclusions of the special master . . . , (B) set aside the findings of fact or

conclusions of law . . . , or (C) remand the petition to the special master for further action in accordance with the court’s direction.” *Id.* § 300aa-12(e)(2). Legal conclusions are reviewed *de novo*, whereas discretionary decisions are reviewed for abuse of discretion. *Munn v. Sec’y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992). The special master’s factual findings are reviewed under the highly deferential “arbitrary and capricious” standard. *Lombardi v. Sec’y of Health & Human Servs.*, 656 F.3d 1343, 1350 (Fed. Cir. 2011); *Tullio v. Sec’y of Health & Human Servs.*, 149 Fed. Cl. 448, 456 (2020) (“The arbitrary and capricious standard is well understood to be the most deferential possible.” (internal quotation marks omitted)).

### III. Petitioners’ Motion For Review

The Vaccine Act provides a framework permitting petitioners to seek compensation for a vaccine-related “illness, disability, injury, or condition” that lasts “more than 6 months.” 42 U.S.C. §§ 300aa-11(c)(1)(C), (c)(1)(D)(i); *see Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010) (“identifying the injury is a prerequisite to the [causation] analysis”). For vaccines administered after October 1, 1988, petitions must be filed within “36 months after the date of the occurrence of the first symptom . . . of such injury.” 42 U.S.C. § 300aa-16(a)(2). For injuries not already recognized by the Vaccine Injury Table, *see id.* § 300aa-14, such as the case at issue here, “the petitioner must prove actual causation by a preponderance of the evidence.” *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013); *see Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010) (holding that “preponderant evidence” necessitates more than a “‘plausible’ or ‘possible’ causal link between the vaccine and the injury”). To prove causation in fact, the petitioner must provide: “(1) a medical theory casually connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). The third *Althen* prong requires “preponderant proof that the onset of symptoms occurred within a framework for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *de Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (emphasis added); *see Veryzer v. Sec’y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (“Merely showing that injury occurred after the administration of a vaccine is insufficient.”).

The [\* \* \*] argue that the Chief Special Master overemphasized A.Y.’s preexisting autism diagnosis when evaluating the varicella vaccine claim. Pet. Mot. at 13–16. Furthermore, the [\* \* \*] contend that the Chief Special Master improperly relied on medical literature and reports not contained in the record, and which the [\* \* \*

\*] argue they did not have an opportunity to address. *Id.* at 16–18. Finally, the [\* \* \*] assert that the Chief Special Master improperly discredited Dr. Gerson’s expert testimony. *Id.* 18–19. While the Court sympathizes deeply with the [\* \* \*] regarding A.Y.’s numerous medical issues, the Court finds that the Chief Special Master’s decision was not arbitrary, capricious, or an abuse of discretion, and, accordingly, the Court sustains his decision for the reasons explained below.

#### **A. The Chief Special Master Did Not Act Arbitrarily By Referencing A.Y.’s Autism Diagnosis**

The [\* \* \*] argue that the Chief Special Master abused his discretion, as “his entire review of the medical records in this case cast it almost exclusively as an autism case, i.e. that Petitioners are alleging A.Y.’s autism was caused by his vaccinations.” Pet. Mot. at 15. The [\* \* \*] note that the Chief Special Master used the terms “autism” and “autism spectrum disorder” a combined 41 times in the decision, that he “is highly critical of two of A.Y.’s treating doctors . . . as they pertain to autism,” and that the Chief Special Master made “several negative statements about the treatments [they] sought for him – for his *autism*.” *Id.* at 13–15 (emphasis in original). In their view, this demonstrates that autism “was the lens through which [the Chief Special Master] viewed the evidence.” *Id.* at 16.

Although the [\* \* \*] invoke the “abuse of discretion” standard, that standard is limited to discretionary decisions and “rarely come[s] into play.” *Munn*, 970 F.2d at 870 n.10 (holding that exclusion of evidence is subject to abuse of discretion standard); *see also Harding v. Sec’y of Health & Human Servs.*, 146 Fed. Cl. 381, 393–94 (2019) (“contesting a special master’s determination of reasonable attorney’s fees, the applicable standard of review is abuse of discretion”). Because the [\* \* \*] in essence contest the Chief Special Master’s findings of fact, this Court properly evaluates his weighing of the evidence and resulting factual conclusions pursuant to the “arbitrary and capricious” standard of review. *See Munn*, 970 F.2d at 870 n.10.

Accordingly, on a motion to review, this Court “do[es] not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or credibility of the witnesses—these are all matters within the purview of the fact finder.” *Porter v. Sec’y of Health & Human Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *see Cedillo v. Sec’y of Health & Human Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010) (“Our role is not to second guess the Special Master’s fact-intensive conclusions[.]” (brackets and quotation marks omitted)). Because “the special masters have broad discretion to weigh evidence and make factual determinations,” *Dougherty v. Sec’y of Health & Human Servs.*, 141 Fed. Cl. 223, 229 (2018), “reversible error will be extremely difficult to demonstrate.” *Hibbard v. Sec’y of Health & Human Servs.*,

698 F.3d 1355, 1363 (Fed. Cir. 2012). In sum, “if the special master’s conclusion is based on evidence in the record that is not wholly implausible, [this Court is] compelled to uphold that finding as not being arbitrary and capricious.” *Deribeaux v. Sec’y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013) (brackets and quotation marks omitted).

The Court does not deny that the Chief Special Master continuously references A.Y.’s autism throughout his decision. And, indeed, the Court concurs with Petitioners that the case law does not “support the denial of a petitioners [sic] claim on the basis of preexisting autism.” Pet. Mot. at 16. That is, of course, where a petitioner’s claim does not involve an allegation that a vaccine precipitated autism. *See, e.g., Yates v. Sec’y of Health & Human Servs.*, 150 Fed. Cl. 575, 577–78 (2020) (reviewing petition of individual with “a history of autism” for injuries allegedly caused after receiving the Menactra vaccine); *Spahn v. Sec’y of Health & Human Servs.*, 133 Fed Cl. 588, 591–92 (2017) (reviewing petition of individual, who was diagnosed with autism, claiming that tetanus-diphtheria vaccine significantly aggravated obsessive-compulsive disorder). In this case, however, the [\* \* \*] asserted two claims for compensation based on the alleged reactivation of the varicella vaccine: (1) A.Y.’s alleged varicella skin rash, and (2) *significant aggravation of A.Y.’s autism-related behavioral and intestinal issues*. *See A.Y.*, 2020 WL 5351342 at \*1. Thus, to be fair, the [\* \* \*] themselves placed A.Y.’s autism at the center of their petition for compensation. The Chief Special Master was, in turn, required to evaluate the onset and severity of A.Y.’s autism-related issues in determining the legitimacy of the significant aggravation claim. Once the [\* \* \*] submitted related medical records and supporting materials into the record, it is unsurprising (if not required) that the Chief Special Master also considered whether the myriad of autism treatments provided a possible alternative explanation for the alleged skin rash or exacerbated behavioral and other symptoms.

Arguing that the Chief Special Master mischaracterized Dr. Gershon’s expert opinion, the [\* \* \*] are highly critical of the Chief Special Master’s observation that “[t]he causation theory in this case has numerous ‘echoes’ with such previously-litigated [autism] claims.” Pet Mot. at 16 (emphasis added) (quoting *A.Y.*, 2020 WL 5351342 at \*24 n.34). And, when read in a vacuum, that comment certainly appears to be supportive of the [\* \* \*]’ argument. A closer examination of the Chief Special Master’s decision, however, demonstrates that he appropriately qualified his observation, as follows:

My determination not to hold a hearing was also influenced in minor part by the undeniable fact that this case presents circumstances common to many other ASD injury cases previously litigated in the Program, *in which well meaning*

*parents pursue questionable medical treatments that may themselves have unpredictable complications, while also insisting that vaccination played some role in the child's condition. . . . The causation theory in this case has numerous "echoes" with such previously-litigated claims—in particular to the extent it sought to establish that certain aspects of A.Y.'s ASD-related behaviors were worsened by the purported varicella reactivation—and those parallels underscored for me why resolution on the papers was preferable to hearing.*

A.Y., 2020 WL 5351342 at \*24 n.34 (emphasis added) (internal citation omitted). The "echoes" that the Chief Special Master referenced were the [\* \* \*]' significant aggravation claim of A.Y.'s preexisting behavioral issues and the myriad of controversial treatments that A.Y. received during the seven years in between vaccination and the alleged reactivation. Additionally, the Chief Special Master does not appear to have relied on similarities between the present case and previous autism cases to deny the [\* \* \*]' petition; rather his observation was made merely in the context of deciding that a hearing was unnecessary. In sum, the Chief Special Master did not act arbitrarily in weighing all of the autism-related medical information that was provided by the [\* \* \*].

#### **B. The Chief Special Master Did Not Commit Reversible Error By Consulting Medical Literature Outside Of The Pleadings**

The [\* \* \*] next contend that the Chief Special Master abused his discretion by improperly consulting medical literature, websites, and reports not submitted by Petitioners or the government. Pet. Mot. at 16–18. The [\* \* \*] assert that due process considerations required the Chief Special Master to have provided the [\* \* \*] with a meaningful opportunity to examine and address all materials that he relied upon in reaching his decision to deny A.Y. compensation. *Id.* The [\* \* \*] maintain that they were not provided with such an opportunity, and, thus, that the Chief Special Master's decision should be reversed. *Id.*

Our appellate court, the United States Court for the Federal Circuit, has held that "[i]t is axiomatic that special masters in vaccine cases have great leeway in building a record for decision." *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 65 (2010), *aff'd*, 420 F. App'x 973 (Fed. Cir. 2011). In admitting evidence for the record, special masters are provided "flexible and informal standards," 42 U.S.C. § 300aa-12(d)(2)(B), and are "not . . . bound by common law or statutory rules of evidence." Vaccine Rule 8(b)(1). This flexibility must be balanced with the directive that "core concepts of due process apply to proceedings before a special master." *Davis*, 94 Fed. Cl. at 65. In that

regard, a special master is required to “provide adequate notice to the parties of evidentiary issues” and “to decide [the case] on the record.” *Id.* (citing 42 U.S.C. §§ 300aa-12(d)(3)(B)(iv),(v), and 300aa-13(a)(1)); *see Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 778 (2006) (“Moreover, consistent with due process, this fairness surely entails notice and an effective opportunity to be heard at a meaningful time and in a meaningful manner.”).

Within this framework, the Federal Circuit has recognized that it may be appropriate for special masters to take judicial notice of certain facts without notifying the parties. *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1526 (Fed. Cir. 1991); *see Rodriguez v. Sec'y of Health & Human Servs.*, 91 Fed. Cl. 453, 460 (2010) (“the [Federal Circuit] has approved the taking of judicial notice in a case arising under the Vaccine Act”). Judicial notice of facts that are “not subject to reasonable dispute” from “sources whose accuracy cannot reasonably be questioned,” does not violate due process, the Federal Circuit reasoned, because the party still has the opportunity to challenge any prejudice arising from that information on review before the Court of Federal Claims. *Hines*, 940 F.2d at 1526. Indeed, the Federal Circuit noted that “[w]ell-known medical facts are the types of matters which judicial notice may be taken.” *Id.*

In his decision, the Chief Special Master cited seven sources that were not presented by the parties. *See A.Y.*, 2020 WL 5351342 at \*17-\*18, \*21, \*21 n.29. Specifically, in the section of his decision entitled “Varicella Reactivation and Relevant Varicella Vaccine Cases,” the Chief Special Master considered two medical textbooks – *Atlas of Pediatric Physical Diagnosis* 444 (5th ed. 2007) and *Nelson Textbook of Pediatrics* 1579–84 (R. Kliegman et al., 20th ed. 2016) – to establish generally accepted propositions about the varicella virus, including its symptoms, potential for latency and reactivation, and common treatments. *Id.* at \*17. Because this information was sourced in two medical textbooks, “both are within the bounds of judicial notice as they contain commonly known information which need not be proved.” *Griffin v. Sec'y of Health & Human Servs.*, 124 Fed. Cl. 101, 107 (2014) (citing *B.V.D. Licensing Corp. v. Body Action Design*, 846 F.2d 727, 728 (Fed. Cir. 1988)).

The Chief Special Master also cited three websites not presented by the parties. *A.Y.*, 2020 WL 5351342 at \*18, \*21. One such website was a government website – the Federal Drug Administration website. *Id.* at \*21. The Chief Special Master consulted that website for generally available information about the viral contents of the varicella vaccine (known as varivax). *Id.* The other two websites were the Mayo Clinic website and an online microbiology journal available on a website associated with the National Institutes of Health. *Id.* at \*18. As with the medical dictionaries, the Chief Special Master utilized these online sources to further explain the ability of the varicella virus to remain latent and reactivate after lengthy periods of inactivity. *Id.* Again, because the

accuracy of this information available through these reputable sources is not seriously subject to debate, the Chief Special Master did not err in taking judicial notice of their contents.<sup>4</sup> *See Griffin*, 124 Fed. Cl. at 107.

More significantly, in the [\* \* \*] motion for review – other than asserting that they were not afforded an opportunity to examine these medical textbooks and online materials before the Chief Special Master rendered his decision – the [\* \* \*] fail to explain (or even allege) precisely how they were prejudiced by the Chief Special Master’s consideration of these materials.<sup>5</sup> *See Pet. Mot.* at 16–18. On the contrary, as the government correctly notes in its response, these materials were at least partially “to the advantage of petitioners” in that they provided some factual support about the latency and reactivation capabilities of the varicella virus. *Resp. Br.* at 11.

Finally, the Chief Special Master considered two of the references footnoted by the Gershon Article, which the [\* \* \*] submitted for the record as part of Dr. Honaker’s expert opinion. *A.Y.*, 2020 WL 5351342 at \*21 n.29. For the proposition that varicella vaccine could remain latent and reactivate in the same manner as varicella virus, the Gershon Article referred to two medical journal articles: I. Kamiya et al., *Viremic Phase in Leukemic Child After Live Varicella Vaccination*, 89 Pediatrics 147 (1992), and S. Weinmann et al., *Incidence and Clinical Characteristics of Herpes Zoster Among Children in the Varicella Vaccine Era*, 208 J. Infectious Disease 1859 (2013). Upon reviewing those unfiled articles, the Chief Special Master observed, in a footnote, that neither article “appear to stand strongly for the proposition that a vaccine administered years before could have the same reactivation potential as the wild virus” and thus “does not identify strong support for Dr. Gershon’s assertions.” *A.Y.*, 2020 WL 5351342 at \*21 n.29. These articles, however, were not filed by the [\* \* \*] and the Chief Special Master did not notify them that he would consider or otherwise address these sources as part of his decision. *See Pet. Mot.* at 17 n.12 (asserting that the Chief Special Master’s critique of these sources was prejudicial to their claim).

This gives the Court some pause. On the one hand, a learned colleague of this Court has concluded, on facts similar to those at issue here, that it is improper for a special master to undertake a review of materials that were not expressly submitted for

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<sup>4</sup> The Court notes, however, that it would be inappropriate for a special master to take judicial notice of information posted on unreliable websites. *See Campbell*, 69 Fed. Cl. at 780-82 (finding that a special master committed reversable error in relying on information, not submitted by the parties, from Wikipedia and other websites which contained reliability disclaimers).

<sup>5</sup> Because the [\* \* \*] have not attempted to respond substantively to the medical information that the Chief Special Master consulted, such failure likely constitutes waiver. *See Hines*, 940 F.2d at 1526; *see also* Vaccine Rule 8(f).

the record. *See Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 64–66 (2010) (Lettow, J.) (holding that it was improper for the special master to draw an adverse inference from a medical study, which was cited in an article included in the record, not itself submitted by the petitioner). On the other hand, in the special master’s role as fact finder, he or she must examine an expert opinion’s analysis and not just accept the expert’s *ipse dixit* conclusions. *See Isaac v. Sec'y of Health & Human Servs.*, 108 Fed. Cl. 743, 768 (2013) (“[A] special master does not need to credit expert opinion testimony that is connected to the existing data or methodology only by the *ipse dixit* of the expert . . . .” (internal citation marks and footnote omitted)). To the extent that the Gershon Article effectively incorporated other articles by reference to support its analysis, the Court cannot conclude that the Chief Special Master improperly reviewed those cited articles as well. *Cf. Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2010) (“Incorporation by reference provides a method for integrating material from various documents into a host document . . . by citing such material in a manner that makes clear that the material *is effectively part of the host document as if it were explicitly contained therein.*” (emphasis added)); *Love Terminal Partners v. United States*, 97 Fed. Cl. 355, 385 (2011) (noting that “Courts ‘have allowed consideration of matters incorporated by reference or integral to the claim’” in deciding a motion to dismiss (quoting 5B Charles A. Wright & Arthur R. Miller, *Federal Practice & Procedure* § 1357 (3d ed. 2004))). If a special master were not permitted to evaluate the substance and articulated rationale supporting a particular piece of scientific evidence, that would be tantamount to concluding that a special master must accept an expert’s *ipse dixit*. Put differently, the Court does not see why a special master’s review of citations that *Petitioners themselves effectively have placed into the record* is all that different from checking an expert’s math.

The Court need not definitively resolve that issue, however, because just as Judge Lettow ultimately concluded in *Davis*, 94 Fed. Cl. at 66, even if the citations the Chief Special Master considered are deemed outside of the record – and thus improperly considered – it was harmless error. When “the special master’s decision was based on a number of factors and [petitioner] has not shown that the reliance on the [information] . . . was likely critical to the result,” such a mistake constitutes “harmless error” and does not justify reversing the special master’s decision. *Hines*, 940 F.2d at 1526; *see Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1356 n.2 (Fed. Cir. 2010) (holding that the special master taking judicial notice of table of brain weights “was harmless[, as t]his table was not the only fact the special master relied on, or even the most important one, in declining to credit Dr. Shane’s theory” (internal citation omitted)); *see also Broekelschen*, 618 F.3d at 1346–47 (characterizing assessment of witness demeanor as “at most . . . harmless error”); *Cedillo*, 617 F.3d at 1342–44 (“any error in

considering the . . . testimony was, in fact harmless, as it did not affect the outcome of the proceeding").

In this case, the Court concludes that there is significant other evidence *in the record*, as detailed in the following section, that the Chief Special Master relied upon in rejecting Dr. Gershon's causation theory in this case. *See infra* Section III.C. Moreover, the Chief Special Master made his observations of the Gershon Article based on his review of the two unfiled articles in a footnote, not in the body of his decision, further indicating that these referenced articles played a minimal role in his ultimate decision. Given the totality of the record evidence and the [\* \* \*] failure to show that the Chief Special Master substantially relied on his outside-the-record research in reaching his ultimate decision, the Court concludes that, even if this action was improper, it was harmless error.

### **C. The Chief Special Master Did Not Act Arbitrarily In His Evaluation Of Dr. Gershon's Expert Opinion**

"[A]s the finder of fact, the special master [is] responsible for assessing the reliability of [the expert's] testimony by looking for reliable medical or scientific support." *Lalonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1340 (Fed. Cir. 2014). The special master "is not required to accept an expert's opinion simply because the expert is found qualified to opine in a medical or scientific discipline." *Bean-Sasser v. Sec'y of Health & Human Servs.*, 127 Fed. Cl. 161, 165 (2016). While "[a] finding of preponderant evidence of causation in fact may be based on medical opinion alone[.] . . . the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Davis*, 94 Fed. Cl. at 63 (internal citation omitted) (quoting *Moberly*, 592 F.3d at 1324); *see Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) ("A [special master] may conclude that there is simply too great an analytical gap between the data and the opinion proffered." (quotation omitted)). When it is evident that the special master "clearly considered all of the pertinent evidence provided[, t]his Court cannot reweigh the evidence at hand to arrive at a new conclusion without infringing upon the great deference afforded special masters in making compensation decisions." *Caruso v. Sec'y of Health & Human Servs.*, 137 Fed Cl. 386, 394 (2018) (emphasis in original).

The [\* \* \*] contend that the Chief Special Master did not afford appropriate deference to Dr. Gershon's expert testimony that: (1) it is medically acceptable that the varicella vaccine could reactive many years later; and (2) A.Y. was actively experiencing a varicella infection in 2015. Pet. Mot. at 18-20. Petitioners attempt to frame this argument as the Chief Special Master's having "committed legal error" by raising their "burden of proof by requiring direct evidence and scientific confirmation . . . rather than

a preponderance of the evidence.” Pet. Mot. at 18, 20. Under such a theory, this Court would need to undertake a *de novo* review. *See Munn*, 970 F.2d at 870 n.10. However, a fair reading of the [\* \* \*] argument reveals that they essentially contest the Chief Special Master’s assessment of Dr. Gershon’s credibility. Accordingly, as with any time this Court is asked to reweigh the special master’s evaluation of an expert’s persuasiveness, this claim is properly viewed under the deferential “arbitrary and capricious” standard of review. *See Milik v. Sec’y of Health & Human Servs.*, 822 F.3d 1367, 1380 (Fed. Cir. 2016).

Petitioners assert that Dr. Gershon is “a leading expert in the field [of varicella latency and reactivation] who remains unchallenged in the record.” Pet. Mot. at 19. The Chief Special Master, however, acknowledged both Dr. Gershon’s credentials and her conclusion that it was medically accepted that the varicella virus could remain dormant and reactivate years later. A.Y., 2020 WL 5351342 at \*7, \*17-\*18. Nevertheless, based on the record, the Chief Special Master also found that “Petitioners have offered no evidence establishing *what period of time* from vaccination to reactivation would be medically acceptable” in terms of attributing the reactivation to the vaccine. *Id.* at \*21 (emphasis in original). The Chief Special Master further expanded on this point, noting that, because “varicella vaccine (which includes a live but attenuated varicella virus strain) is intended to be *less* virulent than the wild virus . . . it cannot simply be assumed that the same latency periods apply to both.” *Id.* (emphasis in original). He also determined that, given “the timeframe in question (from vaccination to onset) is so lengthy,” Dr. Gershon failed to appropriately consider all the various treatments that A.Y. received during that time. *Id.* at \*22. In light of those myriads of treatments, many of which the Chief Special Master characterized as “lack[ing] general medical community or [autism] treater acceptance,” he was unable to conclude that there was “no possible intervening triggers” for the skin rash. *Id.* (emphasis in original).

Regarding the [\* \* \*] other contention that “[o]bjective medical testing showed that A.Y. had an active [varicella] infection,” Pet. Mot. at 19, the Chief Special Master explained that the record entirely lacks a confirmed diagnosis that the marks and rashes which A.Y. experienced in 2015 were actually varicella. A.Y., 2020 WL 5351342 at \*20. Additionally, the Chief Special Master observed, that A.Y. did not suffer from other indicia of a varicella infection, like fever, and that “[n]o blood testing, antibody findings, or other serologic evidence has been offered to corroborate that a varicella infection existed as of the winter of 2015.” *Id.* On the contrary, the Chief Special Master noted Dr. Tachdjian’s opinion that A.Y.’s antibody tests “were *not* consistent with the conclusion that A.Y. had experienced a varicella infection.” *Id.* (emphasis in original). Furthermore, even assuming that the skin rash was varicella, the Chief Special Master noted that, because the record revealed that the rash cleared up quickly with Acyclovir,

there was no basis for recovery pursuant to the Vaccine Act's six-month rule. *Id.* (citing 42 U.S.C. § 300aa-11(c)(1)(D)(i)). Conversely, the Chief Special Master reasoned, to the extent that the record demonstrated that A.Y. had been using Acyclovir "throughout his life," that would suggest that he had initial symptoms of varicella infections earlier in life, prior to 2015, thus barring compensation under the Vaccine Act's three-year statute of limitations period. *Id.*

While the Chief Special Master acknowledged Dr. Gershon's findings of varicella strains in A.Y.'s intestine during the winter of 2015, the Chief Special Master reasoned that the report suffered from "reliability concerns." *Id.* Dr. Gershon had created the report in 2017, two years after her review of the 2015 biopsy report and included "no substantive back-up data for the findings has been filed, making it impossible to confirm the accuracy of these representations." *Id.* Moreover, the [\* \* \*] did not provide any further corroborating evidence that the alleged evidence of the varicella strains in A.Y.'s intestine related to virus reactivation, especially when considering all the possible intervening causes during the prior seven years. *Id.*

In sum, while the [\* \* \*] clearly would have preferred that the Chief Special Master have afforded more weight to Dr. Gershon's theory linking latency and reactivation of the varicella virus and the varicella vaccine and her analysis of A.Y.'s 2015 biopsy, the Chief Special Master evaluated all the medical information available in the record in reaching his reasoned conclusion. The Chief Special Master did not simply disagree with Dr. Gershon's conclusions; rather, he scrutinized her theory and accompanying analysis as applied to the specific facts of this case "and reached the reasonable conclusion that, in the absence of supporting studies or other evidence, [her] expert testimony was unreliable." *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 133-34 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012). Because "[d]etermining what weight should be afforded to the testimony of a fact witness, expert witness, or medical records is a finding well within the discretion of the Special Master, . . . this Court will not endeavor to infringe upon that well-established discretion." *Caruso*, 137 Fed. Cl. at 393.

#### CONCLUSION

For all the above reasons, the Court **DENIES** Petitioners' motion for review and sustains the Chief Special Master's decision. The Clerk shall enter **JUDGMENT** for Respondent accordingly.

**IT IS SO ORDERED.**

s/ Matthew H. Solomson  
 Matthew H. Solomson  
 Judge